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RICHARD W. WIEKING, CLERK
U.S. DISTRICT COURT
NO. DIST. OF CA.

5 Attorneys for Defendants

6 SMITHKLINE BEECHAM CORPORATION dba
7 GLAXOSMITHKLINE and McKESSON
8 CORPORATION

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FEB 25 2008

RICHARD W. WIEKING,
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
JL

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

11 MOHINDER KHANNA

CV 08

1131

12 Plaintiff,

13 v.

14 SMITHKLINE BEECHAM
15 CORPORATION d/b/a
16 GLAXOSMITHKLINE, McKESSON
17 PHARMACY SYSTEMS, and DOES ONE
through FIFTEEN, inclusive,

18 Defendants.

19 NOTICE OF REMOVAL AND
REMOVAL ACTION UNDER 28 U.S.C.
§ 1441(B) (DIVERSITY) and 28 U.S.C. §
1441(C) (FEDERAL QUESTION) OF
DEFENDANT SMITHKLINE
BEECHAM CORPORATION dba
GLAXOSMITHKLINE

20 TO THE CLERK OF THE COURT:

21 Defendant Smithkline Beecham Corporation dba GlaxoSmithKline ("GSK"),
22 hereby removes to this court the state action described below. Removal is warranted
23 under 28 U.S.C. § 1441 because this is an action over which this Court has original
jurisdiction under 28 U.S.C. §§ 1331 and 1332.

24 I. BACKGROUND

25 1. On February 19, 2008, Plaintiff Mohinder Khanna ("Plaintiff"),
26 commenced this action in the Superior Court of the State of California for the County of
27 San Francisco. A true and correct copy of the Complaint in the action is attached as
28

1 Exhibit "A" to the Declaration of Krista L. Cosner in Support of Notice of Removal and
 2 Removal Action under 28 U.S.C. § 1441(b) (Diversity) and 28 U.S.C. § 1441(c) (Federal
 3 Question) of Defendant SmithKline Beecham Corporation dba GlaxoSmithKline
 4 (hereinafter "Cosner Decl.").

5 2. Neither defendant has been served with Plaintiff's Complaint.¹ Cosner
 6 Decl. ¶ 3.

7 3. There have been no additional proceedings in the state court action. Cosner
 8 Decl. ¶ 2.

9 4. This is one of many cases that have been filed recently in both federal and
 10 state court across the country involving the prescription drug Avandia®. Cosner Decl. ¶
 11 6.

12 5. On October 16, 2007, the Judicial Panel on Multidistrict Litigation
 13 ("JPML") issued an order directing that then-pending Avandia-related cases be
 14 transferred and coordinated for pretrial proceedings in the United States District Court for
 15 the Eastern District of Pennsylvania, before the Honorable Cynthia M. Rufe, pursuant to
 16 28 U.S.C. § 1407. *See Transfer Order, In re Avandia Marketing, Sales Practices and*
 17 *Products Liability Litigation*, MDL 1871 (E.D.P.A.) (a true and correct copy of which is
 18 attached as Exhibit "B" to Cosner Decl.). Additional Avandia-related cases pending in
 19 federal court, which are common to the actions previously transferred to the Eastern
 20 District of Pennsylvania and assigned to Judge Rufe, are treated as potential tag-along
 21 actions. *See id.; see also* Rules 7.4 and 7.5, R.P.J.P.M.L. 199 F.R.D. 425, 435-36 (2001).
 22 GSK intends to seek the transfer of this action to that Multidistrict Litigation, *In re*
 23 *Avandia Marketing, Sales Practices and Products Liability Litigation*, MDL 1871, and
 24 shortly will provide the JPML with notice of this action pursuant to the procedure for
 25 "tag along" actions set forth in the rules of the JPML. Cosner Decl. ¶ 7.

26
 27 1 Defendant GSK notes that a notice of intent to bring a Consumer Legal Remedies Act
 28 ("CLRA") action was sent to defendant McKesson Corporation pursuant to California law. This letter has
 no bearing on service of plaintiff's complaint.

1 6. As more fully set forth below, this case is properly removed to this Court
 2 pursuant to 28 U.S.C. § 1441 because GSK has satisfied the procedural requirements for
 3 removal and this Court has subject matter jurisdiction over this action pursuant to 28
 4 U.S.C. §§ 1331 and 1332.

5 **II. DIVERSITY JURISDICTION**

6 7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332
 7 because this is a civil action in which the amount in controversy exceeds the sum of
 8 \$75,000, exclusive of costs and interest, and is between citizens of different states.

9 A. **Diversity Of Citizenship**

10 8. Plaintiff, Mohinder Khanna, is a citizen of the State of California. Cosner
 11 Decl., Exh. A, ¶ 2.

12 9. GSK is, and was at the time Plaintiff commenced this action, a corporation
 13 organized under the laws of the Commonwealth of Pennsylvania with its principal place
 14 of business in Philadelphia, Pennsylvania, and therefore, is a citizen of Pennsylvania for
 15 purposes of determining diversity. 28 U.S.C. § 1332(c)(1). Cosner Decl. ¶ 8.

16 10. For the reasons set forth below, the remaining named defendant –
 17 McKesson Corporation (incorrectly sued as McKesson Pharmacy Systems), a Delaware
 18 corporation, with its principal place of business in San Francisco, California – has not
 19 been “properly joined and served,” and is otherwise fraudulently joined. *See Declaration*
 20 of Greg Yonko paragraph 3, attached as Exhibit C to Cosner Decl. Therefore, its
 21 citizenship must be ignored for the purpose of determining the propriety of removal.²
 22 *See McCabe v. General Foods*, 811 F.2d 1336, 1339 (9th Cir. 1987); *Waldon v. Novartis*
 23 *Pharmaceuticals Corp.*, 2007 U.S. Dist. LEXIS 45809 (N.D. Cal. June 18, 2007).

26 2 GSK notes that the California citizenship of Mohinder Khanna is not diverse from that of
 27 McKesson. However, as set forth, the citizenship of McKesson must be ignored because McKesson is a
 28 fraudulently joined defendant. When McKesson’s citizenship is disregarded, there is complete diversity
 of citizenship.

1 **B. The Amount In Controversy Requirement Is Satisfied**

2 11. It is apparent on the face of the Complaint that Plaintiff seeks an amount in
3 controversy in excess of \$75,000, exclusive of costs and interest.

4 12. Plaintiff alleges that as a result of his Avandia use, he has “suffered cardiac
5 congestive heart failure, heart attack, macular degeneration and serious, painful
6 permanent injury to his heart.” Cosner Decl. Exh. A, ¶ 27.

7 13. Plaintiff seeks to recover general damages; medical, hospital, and incidental
8 expenses; amounts for loss of earnings and loss of earning capacity, as well as punitive
9 and exemplary damages. *See Cosner Decl. Exh. A, Prayer for Relief.*

10 14. Punitive damages are included in the calculation of the amount in
11 controversy. *See Bell v. Preferred Life Assurance Society*, 320 U.S. 238, 240 (1943).

12 15. Given the allegations set forth above, the face of the Complaint makes clear
13 that Plaintiff seeks an excess of \$75,000, exclusive of interest and costs. *See Simmons v.*
14 *PCR Tech.*, 209 F. Supp. 2d 1029, 1031 (N.D. Cal. 2002).

15 **C. The Citizenship of McKesson Must Be Ignored Because McKesson
16 Has Not Been Properly Joined and Served**

17 16. Under 28 U.S.C. § 1441(b), an action is removable only if none of the
18 parties in interest, *properly joined and served* as defendants, is a citizen of the State in
19 which such action is brought. 28. U.S.C § 1441(b) (emphasis added).

20 17. McKesson, although a citizen of California, has not yet been served with
21 the Complaint in this case. Cosner Decl., ¶ 3.

22 18. Accordingly, because there is complete diversity of citizenship and because
23 no “properly joined and served defendant” is a citizen of this State, it is appropriate that
24 this action be removed to this Court. *See Waldon v. Novartis Pharmaceuticals Corp.*,
25 2007 U.S. Dist. LEXIS 45809 (N.D. Cal. June 18, 2007); *see also* 28 U.S.C. § 1441(b).

26 **D. The Citizenship Of McKesson Must Be Ignored Because McKesson Is
27 Fraudulently Joined**

28 19. A defendant is fraudulently joined, and its presence in the lawsuit is
ignored for purposes of determining diversity, “if the plaintiff fails to state a cause of

1 action against the resident defendant, and the failure is obvious according to the settled
 2 rules of the state.” *Morris v. Princess Cruises, Inc.*, 236 F.3d 1061, 1067 (9th Cir. 2001);
 3 *see also Hamilton Materials, Inc. v. Dow Chemical Corporation*, 494 F.3d. 1203, 1206,
 4 2007 WL 2080179 at *1 (9th Cir. 2007).

5 20. McKesson is fraudulently joined because Plaintiff has failed to make any
 6 material allegations against it. *See Brown v. Allstate Insur.*, 17 F. Supp. 2d 1134, 1137
 7 (S.D. Cal. 1998) (finding in-state defendants fraudulently joined where “no material
 8 allegations against [the in-state defendants] are made”).

9 21. With respect to McKesson, Plaintiff’s only allegation is that McKesson is,
 10 and was, engaged in the business of marketing, distributing, promoting, advertising and
 11 selling Avandia...” Cosner Decl. Exh. A, ¶ 5. Notably, however, Plaintiff fails to allege
 12 that he ingested Avandia that was distributed by McKesson, compelling the conclusion
 13 that Plaintiff has fraudulently joined McKesson in an attempt to defeat diversity
 14 jurisdiction. *See e.g., Lyons v. American Tobacco Co.*, No. Civ. A. 96-0881-BH-S, 1997
 15 U.S. Dist. LEXIS 18365 (S.D. Ala. 1997) (holding that there is “no better admission of
 16 fraudulent joinder of [the resident defendant]” than the failure of the plaintiff “to set forth
 17 any specific factual allegations” against them). Plaintiff cannot cure this deficiency by
 18 relying, as he does in the balance of his complaint, on allegations directed towards
 19 “Defendants.”

20 22. In the body of the Complaint, Plaintiff asserts claims of: (1) strict products
 21 liability – failure to warn; (2) negligence; (3) breach of implied warranty; (4) breach of
 22 express warranty; (5) fraud; (6) fraud by concealment; (7) negligent misrepresentation;
 23 and (8) violations of the Consumer Legal Remedies Act, Civil Code §1750, *et seq.* In
 24 these allegations, Plaintiff avers that collectively, “Defendants,” defectively designed and
 25 manufactured Avandia and made misrepresentations about the drug; failed to adequately
 26 and properly test and inspect Avandia; failed to use reasonable care in the labeling,
 27 marketing, selling, advertising and promoting of Avandia; concealed known risks and
 28 failed to provide adequate warnings and labeling. Cosner Decl. Exh. A

1 23. These claims are substantively based on the design and manufacture of
 2 Avandia, the adequacy of pre-clinical testing and post-marketing surveillance, failure to
 3 warn, fraudulent concealment, and misrepresentation. As a wholesale distributor of
 4 Avandia, McKesson played no role whatsoever in its promotion, marketing or
 5 advertising. All McKesson did was pass along unopened boxes of Avandia, in
 6 unadulterated form, to hospitals and other businesses in the healthcare industry. *See*
 7 Cosner Decl. Exh. C, ¶¶ 6-7.³

8 24. Further, based on the “learned intermediary” doctrine, McKesson bore no
 9 duty to warn Plaintiff. The “learned intermediary” doctrine, the foundation of
 10 prescription drug product liability law, provides that the duty to warn about a drug’s risks
 11 runs from the manufacturer to the physician (the “learned intermediary”), and then from
 12 the physician to the patient. *See Brown v. Superior Court (Abbott Labs.)*, 44 Cal. 3d
 13 1049, 1061-62, n.9 (1988); *Carlin v. Superior Court (Upjohn Co.)*, 13 Cal. 4th 1104, 1116
 14 (1996). It is the physician, and only the physician, who is charged with prescribing the
 15 appropriate drug and communicating the relevant risks to the patient. *See Brown*, 44 Cal.
 16 3d at 1061-62.

17 25. GSK and the FDA prepared the information to be included with the
 18 prescription drug, Avandia, with the FDA having final approval of the information that
 19 could be presented. Once the FDA has determined the form and content of the
 20 information, it is a violation of federal law to augment the information. *See* 21 U.S.C.
 21 §331(k) (prohibiting drug manufacturers and distributors from causing the “alteration,
 22 mutilation, destruction, obliteration, or removal of the whole or any part of the labeling”

24 26 27 28 ³ The Declaration of McKesson’s representative, Greg Yonko may be considered by the Court in
 25 determining whether McKesson is fraudulently joined. *Maffei v. Allstate California Ins. Co.*, 412
 26 F.Supp.2d 1049 (E.D. Cal. 2006) (“[t]he court may pierce the pleadings, consider the entire record, and
 27 determine the basis of joinder by any means available”) citing *Lewis v. Time, Inc.*, 83 F.R.D. 455 (E.D.
 28 Cal. 1979) (“it is well settled that upon allegations of fraudulent joinder...federal courts may look beyond
 the pleadings to determine if the joinder...is a sham or fraudulent device to prevent removal”). *See also*
Ritchey v. Upjohn Drug Co., 139 F.3d 1313, 1318-19 (9th Cir. 1998) (evidence may be presented by the
 removing party that there is no factual basis for the claims pleaded against the local defendant).

1 of an FDA-approved drug held for sale); *Brown v. Superior Court*, 44 Cal.3d 1049, 1069
 2 n.12 (noting that the FDA regulates the testing, manufacturing, and marketing of drugs,
 3 including the content of their warning labels). Therefore, any safety and warning
 4 information McKesson had about Avandia would have come from GSK in the form of
 5 FDA-approved packaging and labeling. McKesson could not change the labeling it was
 6 given by GSK as approved by the FDA without violating federal law. No duty can be
 7 found where it requires a party to violate the law to fulfill it.

8 26. As such, given the lack of a causal connection between the injuries alleged
 9 by Plaintiff and McKesson's conduct, as well as the absence of any legal or factual basis
 10 for Plaintiff's claims against McKesson, McKesson's joinder is fraudulent and its
 11 citizenship should be ignored for purposes of determining the propriety of removal.

12 **III. FEDERAL QUESTION JURISDICTION**

13 27. This Court has federal question jurisdiction over Plaintiff's claims under 28
 14 U.S.C. § 1331 and the principles set forth in *Grable & Sons Metal Prods., Inc. v. Darue*
 15 *Eng'g & Mfg.*, 125 S. Ct. 2363 (2005).

16 28. As more fully explained below, Plaintiff has made violations of federal law
 17 critical elements of several of his claims.

18 A. **Plaintiff's Claims Require Construction and Application of the FDCA** 19 **and Its Implementing Regulations**

20 29. Plaintiff's First Cause of Action, "Strict Products Liability – Failure to
 21 Warn," Second Cause of Action, "Negligence," Fourth Cause of Action, "Breach of
 22 Express Warranty," and Seventh Cause of Action, "Negligent Misrepresentation," each
 23 require construction and application of the Federal Food, Drug and Cosmetic Act
 24 ("FDCA") and implementing federal regulations, which govern approval of prescription
 25 drugs and regulate prescription drug manufacturers' public and promotional statements,
 26 including all aspects of warnings and labeling. Cosner Decl., Exh. A.

27 30. As a currently-marketed prescription drug, Avandia is subject to extensive
 28 regulation by the FDA. The FDCA requires the FDA to ensure that "drugs are safe and

1 effective" for their intended uses, 21 U.S.C. § 393(b)(2)(B), in part by "promptly and
 2 officially reviewing clinical research and taking appropriate action on the marketing of
 3 regulated products." 21 U.S.C. § 393(b)(1). The Secretary of the FDA has the authority
 4 to promulgate regulations to enforce the FDCA, which are codified in the *Code of*
 5 *Federal Regulations*, 21 C.F.R. § 200, *et seq.* See 21 U.S.C. § 371(a).

6 31. To accomplish its purpose, the FDA maintains a Center for Drug
 7 Evaluation and Research (the "CDER"). The CDER regulates pharmaceutical
 8 companies' development, testing and research, and manufacture of drugs. The CDER
 9 examines data generated by these companies to conduct a risk/benefit analysis and make
 10 an approval decision. The CDER also ensures truthful advertising for prescription drugs,
 11 in part by approving Package Inserts that properly outline benefit and risk information.
 12 Once drugs are marketed, the CDER continues to monitor them for unexpected health
 13 risks that may require public notification, a change in labeling, or removal of the product
 14 from the market. In short, the CDER evaluates and monitors the effectiveness and safety
 15 of prescription drugs. See <http://www.fda.gov/cder/about/faq/default.htm>.

16 32. Promotional communications to physicians about Avandia are contained
 17 within, and restricted by, warning, labeling, and promotional materials, such as the
 18 Package Insert, that are approved and monitored by the FDA to ensure the provision of
 19 accurate information about the drug's respective risks and benefits. Under federal
 20 regulations, even claims in promotional labeling or advertising must be consistent with
 21 approved labeling. 21 C.F.R. § 202.1(e)(4) (2005).

22 33. The FDA's responsibility to regulate prescription drugs sold in the United
 23 States, and to enforce laws with respect to such drugs, inclusive of the precise content
 24 and format of prescription drug labeling (*e.g.*, the instructions, warning, precautions,
 25 adverse reaction information provided by manufacturers, and marketing materials), is
 26 plenary and exclusive. See 21 U.S.C. § 301, *et seq.*

27 34. Plaintiff has made alleged violations of federal law a critical element of his
 28 claims. Accordingly, Plaintiff's claims necessarily raise substantial federal questions by

1 requiring the Court to construe and apply the FDCA and its implementing regulations.

2 **B. Federal Control of Drug Labeling and Warning**

3 35. On January 24, 2006, the FDA announced a rule that includes a detailed
 4 and emphatic statement of the FDA's intention that its regulation and approval of
 5 prescription drug labeling preempt most state law claims related to the adequacy of
 6 prescription drug warnings because such claims frustrate "the full objectives of the
 7 Federal law." *See Requirements on Content and Format of Labeling for Human*
 8 *Prescription Drug and Biologic Products*, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) ("FDA
 9 believes that under existing preemption principles, FDA approval of labeling under the
 10 act . . . preempts conflicting or contrary State law."). *See also In re Bextra and*
 11 *Celebrex Marketing*, 2006 WL 2374742 (N.D. Cal., August 16, 2006) (Celebrex
 12 decision); *In re Bextra and Celebrex Marketing*, 2006 WL 2472484 (N.D. Cal., August
 13 24, 2006) (Bextra decision);

14 36. Plaintiff alleges that Defendants failed to disclose certain risks of Avandia.
 15 *See e.g.*, Cosner Decl. Exh. A, ¶ 16. This allegation necessarily requires Plaintiff to
 16 establish that the FDA, which has exclusive jurisdiction over the labeling of drugs, would
 17 have approved the warning the Plaintiff alleges should have been given.

18 37. Accordingly, there is a substantial federal question with respect to whether
 19 Plaintiff can claim that GSK violated state law in light of the FDA's control of Avandia's
 20 labeling and warning and its position on conflict preemption.

21 **C. The Federal Interest In Providing A Forum**

22 38. The federal government has a strong interest in having a federal court
 23 decide several of the issues in this case. Among these issues are:

- 24 a. whether any conduct of GSK violated any federal laws or
 25 regulations related to the labeling and marketing of Avandia; and
- 26 b. whether the FDA-approved Avandia label was false and misleading,
 27 as alleged by Plaintiff, and whether a state may impose liability on
 28 GSK for not providing more information regarding alleged risks, as

Plaintiff contends GSK should have done.

39. Plaintiff's claims may be vindicated or defeated only by construction of federal statutes and regulations. The availability of a federal forum to protect the important federal interests at issue is therefore consistent with *Grable*, and determination by a federal court of the substantial and disputed federal issues that lie at the heart of this case would not "disturb any congressionally approved balance of federal and state judicial responsibilities." *Grable*, 125 S. Ct. at 2368.

IV. CONFORMANCE WITH PROCEDURAL REQUIREMENTS

40. This Court has jurisdiction over this matter based on federal question and diversity of citizenship, and the present lawsuit may be removed from the Superior Court of the State of California for the County of San Francisco, and brought before the United States District Court for the Northern District of California pursuant to 28 U.S.C. §§ 1331, 1332 and 1441.

41. Neither GSK nor McKesson has been served with Plaintiff's Complaint. Cosner Decl. ¶ 3. Therefore, this Removal has been timely filed. *See* 28 U.S.C. § 1446(b).

42. Since neither GSK nor McKesson has been “properly joined and served” at the time of filing this Removal, GSK is entitled to removal under the plain language of 28 U.S.C. § 1441(b). *See Waldon v. Novartis Pharmaceuticals Corp.*, 2007 U.S. Dist. LEXIS 45809 (N.D. Cal. June 18, 2007). *See also* 28 U.S.C. § 1441(b); Cosner Decl., ¶ 3.

43. Moreover, although McKesson's consent to remove is not necessary because it is fraudulently joined, McKesson nonetheless consents to removal. Cosner Decl., ¶ 9. See also, e.g., *Easley v. 3M Company, et al.*, 2007 WL 2888335 (N.D. Cal. 2007) citing *Emrich v. Touche Ross & Co.*, 846 F.2d 1190, 1193 n.1 (9th Cir. 1988).

44. The United States District Court for the Northern District of California is the federal judicial district encompassing the Superior Court of the State of California for the County of San Francisco, where this suit was originally filed. Venue therefore is

proper in this district under 28 U.S.C. § 1441(a).

45. Pursuant to the provisions of 28 U.S.C §1446(d), GSK will promptly file a copy of this Notice of Removal with the clerk of the Superior Court of the State of California for the County of San Francisco, where this suit was originally filed.

46. Defendant reserves the right to amend or supplement this Notice of Removal.

WHEREFORE, GSK respectfully removes this action from the Superior Court of the State of California for the County of San Francisco to the United States District Court for the Northern District of California, pursuant to 28 U.S.C. § 1441.

Dated: February 25, 2008

DRINKER BIDDLE & REATH LLP

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